Manufacturing Metrology and Standards for the Health Care Enterprise

Program Manager:	Ram D. Sriram
Phone:	301 975 3507
Email:	sriram@nist.gov
Program Funding:	$595K
FTEs:	2.4

Program Goal

Apply proven MEL manufacturing technology and expertise to healthcare systems, biomedical devices and equipment, and biomedical data management.

Problem

Spending on healthcare in the United States was about 13.2% of the Gross Domestic Product (GDP) in 2000 and continues to grow at the rate of 7.3% per year. Typically U.S. employers offer health insurance benefits to their staff and retirees, making the issue of escalating healthcare costs a major concern. As these costs increase, they raise the cost of doing business and impede our ability to compete globally.

Healthcare and manufacturing share many similar organizational and informational issues. Thus, the healthcare industry as a whole is a customer for the metrology, standard-setting support and technology approaches and solutions that MEL has developed for the manufacturing sector. The healthcare industry needs an infrastructure that will accelerate and enrich development of methodologies to improve organizational and informational support for all aspects of health care delivery.

Approach

There are two dimensions to the program: (1) Healthcare informatics; and (2) Medical devices. Healthcare informatics deals with all the processes or "software" of the healthcare enterprise. Medical devices deal with all the products or "hardware" of the enterprise. The program deals with the following objectives within the above two dimensions:

Healthcare informatics

Enterprise modeling and simulation, Design and production of pharmaceuticals, Biosurveillance, Manufacturing and value chain management

Clinical informatics

Bioinformatics, Medical devices, Mobility devices, Hearing devices, Intelligent assistive surgical devices (medical robots), Surface characterization of biomedical devices, Meso-micro-biodevices, Nano-biodevices

Typical Customers and Collaborators

Healthcare providers and organizations; Process modeling vendors; Healthcare informatics vendors and consultants; Medical device industry; Academic institutions; Government organizations; Various associations and standard bodies.

healthcare

Manufacturing Metrology and Standards for the Health Care Enterprise

Program Goal:

Apply proven MEL manufacturing technology and expertise to healthcare systems, biomedical devices and equipment, and biomedical data management

Program Manager:
Ram D. Sriram

Total FTEs:
2.4

Annual Program Funds:
$595 K

Customer Need & Intended Impact

Spending on healthcare in the United States was about 13.2% of the Gross Domestic Product (GDP) in 2000, which is $1.3 trillion, and continues to grow at the rate of 7.3% per year. This amount will reach $2.8 trillion dollars by 2011 (around 17% of the GDP). These costs are also a major concern for the U.S. industry, as escalating healthcare costs are impeding our ability to compete globally. According to a USA Today article, General Motors (GM) spent $4.5 billion on healthcare in 2002, an increase of nearly 9% from 2001. GM sold 8.4 million vehicles in 2002. In effect, healthcare expenses constituted $535 of the price tag of each GM car. This is reiterated in a recent U.S. Department of Commerce report entitled "Manufacturing in America: A Comprehensive Strategy to Address the Challenges to U.S. Manufacturers." This report cites that rising healthcare costs may prove to be detrimental to our manufacturing industry, with testimonials from various industries.

Healthcare and manufacturing share many similar organizational, technological and informational issues. Thus, the healthcare industry as a whole is a customer for the metrology, standard-setting support and technology approaches and solutions that MEL has developed for the manufacturing sector that are transferable or adaptable to the healthcare sector.

The benefit to the healthcare industry will be an infrastructure for the accelerated and enriched development of improved organizational, technological and informational support methodologies for all aspects of health care delivery. NIST's contributions will enable more effective development and application of biological and medical knowledge to practical problems.

Manufacturing Metrology and Standards for the Health Care Enterprise

Technical Approach & Program Objectives

There are two dimensions to the program: (1) Healthcare informatics; and (2) Medical devices. Healthcare informatics deals with all the processes or "software" of the healthcare enterprise: modeling and simulation, design and production, biosurveillance, manufacturing and its associated supply chains, and information and data management both in clinical practice and biological research. Medical devices deal with all the products or "hardware" of the enterprise: the characterization, design, manufacture, testing, and metrology of medical devices at scales ranging from large equipment to nano-scale drug delivery mechanisms.

This program deals with the following objectives:

(1) Healthcare informatics

Objective #1.1: Enterprise modeling and simulation

Explore the applicability of the modeling and simulation technologies developed in MEL to healthcare systems; explore means for disseminating this information to the shareholders in the healthcare industry.

Objective #1.2: Design and production of pharmaceuticals

Develop representations of pharmaceutical processes, quality measurement methods, and test equipment standards necessary for the specification, characterization, and data interchange involved in the clinical trials, certification, production testing, and manufacture of pharmaceutical products.

Objective #1.3: Biosurveillance

Develop information models and integration technologies, classifications of healthcare terminologies and ontologies, interchange specifications and test methods necessary for the acquisition, characterization, standardization, and validation of public health surveillance information and the dissemination and integration of relevant treatment guidelines to improve the detection and response to disease outbreaks and insidious bioterrorism attacks.

Objective #1.4: Manufacturing and value chain management

Develop interfacing specifications and interaction protocols for integrating manufacturing and e-commerce software solutions into the biomedical device value chain and enhance existing standards for device integration.

Objective #1.5: Clinical informatics

Extrapolate from MEL's experience in information modeling and research supporting information interchange standards development for the manufacturing industry to provide experience, assistance and leadership for related activities in the health care informatics field.

Objective #1.6: Bioinformatics

Adapt and extend NIST's expertise in information modeling, information interchange and standards development in the manufacturing arena to the field of bioinformatics, leading to synergisms with bioinformatics research and practice and consolidation of the bioinformatics knowledge base.

(2) Medical devices

Objective #2.1: Mobility devices

Develop test methods and performance metrics, sensor data, standards and specifications necessary for intelligent assistive devices for wheelchair dependents and the blind.
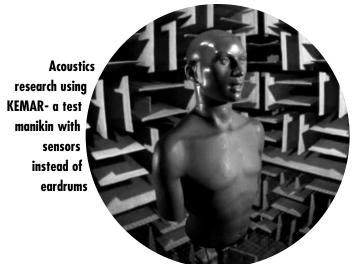
Objective #2.2: Hearing devices

Develop test and measurement methods, data, standards and specifications necessary for the characterization, manufacturing, and testing of hearing devices and related diagnostic equipment.

Objective #2.3: Intelligent assistive surgical devices (medical robots)

Work with an American Standards for Testing of Materials (ASTM) committee, the Food and Drug Administration (FDA), medical robotic research groups and University Hospitals for the establishment of Intelligent Assistive Surgical Devices (Medical Robots) standards. This work will extrapolate on our previous work on industrial robot performance and safety standards, related metrology, instrumentation and artifact and marker design.

Objective #2.4: Surface characterization of biomedical devices

Develop test procedures for characterizing the surfaces of medical devices that relate to device function and failure behavior.

Acoustics research using KEMAR- a test manikin with sensors instead of eardrums

Objective #2.5: Meso-micro-biodevices

Assist in the establishment of meso-micro-biodevices standards. Meso scale devices have components with feature sizes of a few millimeters. Micro-scale devices have components with features, which range between 1 mm and 1 mm and nano-scale devices have components with features, which range between 1 μm and 1 nm.

Objective #2.6: Nano-biodevices

Develop protocols for high-resolution imaging of individual components and associated complexes of the constituents of nanoparticle drug delivery systems (NDS). Demonstrate imaging of the cell transfection process with fixed and live cells using such systems. Nano scale devices have components with features that range between 1 μm and 1 nm.

Manufacturing Metrology and Standards for the Health Care Enterprise

Major Accomplishments

This is a new program initiated in FY 2005. The program builds on the previous accomplishments of all five divisions of MEL, which include the following: an exploratory project on healthcare information interchange through shared ontologies; data representation schemes for proteomics standards; initial studies for robotic wheel chair standards; active participation in the ASTM Intelligent Assistive Surgical Devices (Medical Robots) standards meetings; an exploratory project on nanoparticle imaging which resulted in the acquisition of a scanning probe microscope with biological imaging capabilities; and a major role in the development of American National Standards Institute (ANSI) standard S3.22 "Specification of Hearing Aid Characteristics."

FY2005 Projects

A star (*) in front of a project indicates that the project will be pursued if we are successful in obtaining external funding/collaboration.

Simulation Applicability Study (Objective 1.1)

Prepare a comprehensive report on the applicability of modeling, simulation and visualization concepts developed at NIST/MEL to biological information and processes.

*Pharmaceuticals Industry Involvement Roadmap (Objective 1.2)

Develop a roadmap detailing potential tasks (e.g., similar to those described below) for NIST's role in aiding the pharmaceutical industry. Publish a workshop report on Interoperable Manufacturing Process Specifications to enable interoperability and interchange of manufacture of active ingredients and key intermediates in the production of pharmaceuticals.

Public Health Surveillance Data Interchange Proposal (Objective 1.3)

Develop a proposal for potential funding on standards for the interchange of public health surveillance data and integration of newly disseminated active clinical guidelines into healthcare information systems.

Biomedical Device Industry Needs Study (Objective 1.4)

Conduct a workshop to collect industry needs and prepare a thorough report on biomedical device manufacturers' needs for standards and a roadmap to their achievement. This report will also identify stakeholders, due dates, approaches, and appropriate standard activities for which we should participate.

Clinical Information Standards Plan (Objective 1.5)

Prepare a comprehensive report of all clinical information-oriented standards, their development organizations, their scope and the vocabularies/ontologies they employ. Use the report as the basis for developing a plan for applying NIST's experience to assist in clinical information-oriented standard development and closer harmonization.

*Bioinformatics Framework Proposal (Objective 1.6)

Prepare a comprehensive report reviewing bioinformatics concepts and languages used in bioinformatics, proposing a framework based on information modeling languages, formal ontologies and a common set of concepts enabling better communication.

Wheelchair Standards Core Competency Development (Objective 2.1)

Develop core competencies within MEL to address robotic wheelchair standards organizations intelligently. Prepare and submit a proposal to a healthcare funding organization to further this research.

Hearing Devices Standards Report (Objective 2.2)

Report on development and status of ANSI (The American National Standards Institute) and international (primarily IEC (International Electrotechnical Commission)) standards on hearing devices and related diagnostic equipment.

Standard Test Classes for Human Joint Specimens (Objective 2.3)

Select a few human joint specimens, which will be candidates for NIST standard reference artifacts. These specimens will come from healthy and diseased joints and will form separate standard test classes of the developing standard.

Biomedical Surface Characterization Workshop (Objective 2.4)

Plan and organize a workshop on surface characterization for the biomedical industry.

*Meso-Micro-Biodevice Technology Report (Objective 2.5)

Prepare a brief report describing the status of the Meso-Micro-Biodevices technology and possible opportunities for collaboration with other research groups.

Advanced Nanoparticle Imaging Opportunities (Objective 2.6)

Leverage external funding to demonstrate high-resolution imaging of individual components and associated complexes of the constituents of a NDS (Tf-Lip-p53).

Typical Customers and Collaborators

Healthcare providers and organizations

Cleveland Clinic, Kaiser Permanente, Union Hospital, MD, Mayo Clinic, Partners Healthcare, MA, and others; Pharmaceutical manufacturers such as Eli Lily and Company, Pfizer, Bayer, GlaxoSmithKline, Mylan Laboratories, etc.;

Process modeling vendors

Aspen Technologies; Healthcare informatics vendors and consultants, such as Apelon, Adam Inc., LightPhrama, Synergene Therapeutics, Inc., etc.; Medical device industry;

Academic institutions

University of Pennsylvania, Stanford Medical Informatics, Purdue University, University of Minnesota, University of Michigan, West Virginia University, Carnegie-Mellon University, Johns Hopkins University, University of Pittsburgh, University of Delaware, Georgetown University Medical Center, etc.;

Government organizations

Telemedicine and Advanced Technology Research Center, Fort Dietrick (MD), U.S. Army, U.S. Uniform Health Services, Department of Homeland Security, Various institutes of the National Institutes of Health, Food and Drug Administration, Centers for Disease Control, Veterans Administration, Agency for Healthcare Research and Quality;

Various associations

Radiological Society of North America (RSNA), ANSI, RESNA (Rehabilitation EFY2005 Standards Participation

Manufacturing Metrology and Standards for the Health Care Enterprise

	2003	2004	2005	2006	2007	2008

Themes

- Healthcare informatics
- Medical devices

Principal Activities

- MSID activities
- Healthcare exploratory study
- ISD activities
- MMD activities
- PED activities

- Simulation applicability
- Pharmaceuticals roadmap
- Surveillance proposal
- Device standards needs
- Clinical information plan
- Bioinformatics proposal
- Wheelchair standards
- Hearing device standards
- Reference artifacts
- Surface characterization
- Meso-micro-biodevices
- Imaging nanoparticles

TBD

Deliverables

- Applicability study
- Involvement roadmap
- Interchange proposal
- Competency report
- Industry needs study
- Project plan
- Standards plan
- Reference artifacts
- Framework proposal
- Characterization workshop
- Status report

Impacts

- Better interoperability
- Higher Quality
- Reduced Costs